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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,807	01/17/2001	Maria Palasis	12013/58101	4398

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EXAMINER

THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/10/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/760,807

Applicant(s)

PALASIS, MARIA

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-15, 17-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-12, 14, 15, 17, 19-23 and 25 is/are rejected.
- 7) ☒ Claim(s) 13 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Amendment***

The new matter rejection has been withdrawn with respect to the specification objection regarding "measurable elasticity", the Examiner has withdrawn the objection in view of the applicant's remarks on page 9. The Examiner will treat the language as broadly as the dictionary and in as much as applicant has disclosed. Any element is stuff measurable. But with respect to the dilation bladder being more rigid than the hyperdeformable it is not disclosed as far as applicant has cited on page 10 lines 2-25.

The claim rejection under 35 USC 112, 2<sup>nd</sup> paragraph has been withdrawn in view of the amendment filed 05/16/03.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no support for "balloon" containing "grooves".

### ***Drawings***

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 11/25/02 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of grooves as characterized in the amended figure 5.

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The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown or the feature(s) canceled from the claim(s). **No new matter should be entered.**

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Information Disclosure Statement***

The information disclosure statement filed 04/04/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed.

The information disclosure statement filed 04/04/03 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. As a courtesy, the Examiner has considered the documents on the PTO-892 form.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 7, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 17 are vague and indefinite because "a second internal lumen" has been recited and thus makes it unclear whether it is the same second internal lumen recited in claim 1 or whether it is in addition thereof.

Claim 19 is vague and indefinite because it is unclear what is intended by a "grooved material".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6,8-12,14-15,19, 20-23,25 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. ( U.S. Patent No. 5,295,962).

Crocker et al. teach a system comprising a catheter, a source of fluid, a first inflatable balloon (32) having a measurable elasticity, and a dilatation bladder (30) having a measurable elasticity wherein the elasticity of the first balloon is greater than the dilatation bladder. Crocker et al. disclose the first balloon to be made of an elastic material such as latex located within the first balloon ( 32). See col. 7, lines 16-18. Further, Crocker et al. teach the dilatation bladder to be of a relatively non-elastic material. ( see col. 6, lines 48-53.) and that the application of the device is to dilate a

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stenotic region of a body lumen as desired. ( col. 6, lines 67-col. 7, line 2. ) See col. 4, lines 25-29 .

With respect to "made with a groove material", the Examiner is taking the position that this is a product by process limitation which does not further limit the structure of the device.

### ***Response to Arguments***

Applicant's arguments with respect to claims 20-23,25 have been considered but are not persuasive.

Crock teaches in column 4, lines 25-29, that the inflation can be selectively introduced with respect to applicant's amended limitation of inflating the first balloon without inflating the dilation bladder. Further, the limitation in claims 1 and 12 is considered to be functional and is capable of performing the function. The Examiner is not in agreement with applicant regarding the " forcing a fluid" limitation. ( See page 10 of applicant's remarks). It is disclosed that the drug or other fluid is pressurized and the name itself of "balloon" inherently encompasses forcing fluid to expand/inflate.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

LoAn H. Thanh  
Examiner  
Art Unit 3763

LT

A handwritten signature in black ink, appearing to read "Michael J. Hayes", written in a cursive style.

**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**